K020041

510(K) SUMMARY

MAR 1 4 2002

Submitter's Name, Address, and Phone/Fax Numbers

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Contact Person

Clarence Jones, Ph.D.
8602 Mossford Drive
Huntington Beach, CA 92646

Date 510(k) Summary Prepared

January 4, 2002

Name of the Device

Trade Name: IALUSET® HYDROCOLLOID
Common Name: Hydrocolloid Wound Dressing
Classification Name: Dressing, Wound and Burn, Occlusive (878.4020)

Predicate Device

IALUSET HYDROCOLLOID is substantially equivalent to two other hydrocolloid wound dressings, one from ConvaTec (K881050) and the other from Innovative Technologies (K971126).

Device Description

IALUSET HYDROCOLLOID is a 10 cm x 10 cm wound dressing comprised of an inner layer of hydrocolloids (containing sodium hyaluronate and sodium chondroitin sulfate) which are incorporated into an adhesive matrix and spread between a polyurethane film and a silicone release liner. The dressing absorbs wound exudate, thereby allowing for a moist environment that is conducive to normal wound healing. It does not adhere to the wound, which minimizes both pain and damage to the underlying tissue when the dressing is removed.

Intended Use

IALUSET HYDROCOLLOID may be applied to minor wounds such as abrasions, lacerations, cuts, scalds, or burns by a patient not under the care of a health care

professional, and if under the care of a health care professional, it may be applied to leg ulcers, diabetic ulcers, pressure ulcers, surgical wounds, first and second degree burns, and traumatic wounds. If a patient is unsure of the type of wound he or she has, they should consult with a health care professional before using this product.

Technological Characteristics in Comparison to Predicate Device

Characteristic	IALUSET HYDROCOLLOID	ConvaTec (K881050)	Innovative Technologies (K971126)
Composition	Hydrocolloid plus Polyurethane Film	Hydrocolloid plus Polyurethane Film	Hydrocolloid plus Polyurethane Film
Surface	Extruded & Laminated	Extruded & Laminated	Extruded & Laminated
Indication for Use	Superficial Wounds, Dermal Ulcers, Burns (1^{st} & 2^{nd} Degree), Donor Sites, Postoperative Wounds, Protective Dressings	Superficial Wounds, Dermal Ulcers, Burns (1^{st} & 2^{nd} Degree), Donor Sites, Postoperative Wounds, Protective Dressings	Superficial Wounds, Dermal Ulcers, Burns (1^{st} & 2^{nd} Degree), Donor Sites, Postoperative Wounds, Protective Dressings
Transparent	Yes	Yes	Yes
Self Adhesive	Yes	Yes	Yes
Packaging	Blister Pack	Pouch	Blister Pack
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation

Non-Clinical Performance Data

Extracts of IALUSET HYDROCOLLOID were evaluated in five standard biocompatibility test systems: Cytotoxicity, Primary Skin Irritation, Skin Sensitization, Subchronic Toxicity, and Genotoxicity (Ames). Except for evidence of cytotoxicity in the L929 murine fibroblast assay at the two highest concentrations tested, presumably due to an osmotic effect, IALUSET HYDROCOLLOID extracts were not found to elicit any untoward responses as compared to a vehicle control.

Conclusions

IALUSET HYDROCOLLOID is substantially equivalent to other hydrocolloid wound dressings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2002

Institut Biochimique SA
c/o Clarence E. Jones, Ph.D.
8602 Mossford Drive
Huntington Beach, CA 92646

Re: K020041
Trade/Device Name: Ialuset® Hydrocolloid Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 4, 2002
Received: January 7, 2002

Dear Dr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number: K020041

Device Name: IALUSET® HYDROCOLLOID Wound Dressing

Indications for Use:

For over-the-counter use, IALUSET HYDROCOLLOID may be applied to:

- abrasions
- lacerations
- minor cuts
- minor scalds
- minor burns

Under the supervision of a physician, IALUSET HYDROCOLLOID may also be applied to:

- leg ulcers (venous stasis ulcers, arterial ulcers)
- diabetic ulcers
- pressure ulcers (stage I - IV)
- surgical wounds (postoperative, dermatological excisions, donor sites)
- burns (first and second degree only)
- traumatic wounds

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020041

Concurrence of Office of Device Evaluation, Center for Devices and Radiological Health

Prescription Use: _____ Over-the-Counter Use _____